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NO. 176 P. 1

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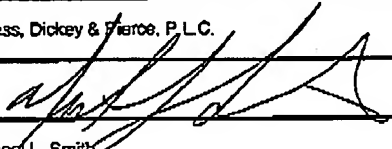
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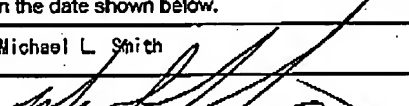
<b>TRANSMITTAL FORM</b> <small>(to be used for all correspondence after initial filing)</small>	Application Number	10/674,094	
	Filing Date	September 29, 2003	
	First Named Inventor	Laurence J. Cull	
	Art Unit	3761	
	Examiner Name	Leslie R. Deak	
Total Number of Pages in This Submission	12	Attorney Docket Number	P03231 (6639-000048/US)

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SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT			
Firm	Harness, Dickey & Pierce, P.L.C.		
Signature			
Printed Name	Michael L. Smith		
Date	June 28, 2007	Reg. No.	35,605

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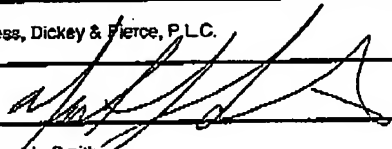
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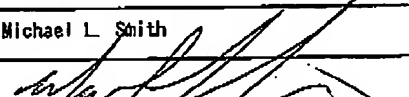
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SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT			
Firm	Harness, Dickey & Pierce, P.L.C.		
Signature			
Printed Name	Michael L. Smith		
Date	June 28, 2007	Reg. No.	35,685

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Typed or printed name	Michael L. Smith	Express Mail Label No.	
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## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

JUN 28 2007

Application of: Laurence J. Cull	)	
	)	Examiner: Leslie R. Deak
Serial No.: 10/674,094	)	
	)	Group No.: 3761
Filed: September 29, 2003	)	
	)	Docket No: P03231
Title: Peristaltic Pump Fitment for Attachment	)	(6639-000048/US)
To an Aspirant Collection Bag	)	

**APPEAL BRIEF**  
**(37 C.F.R. § 41.37)**

Mail Stop Appeal Brief – Patents  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, Virginia 22313

Dear Sir:

Applicant appeals the Final Rejection in the above-identified application dated 31 January 2007, and submits this Appeal Brief in support. Appellant's Brief under 37 C.F.R. 1.192 is enclosed herewith. It is believed that no extensions of time are required. If any other fees, including any extensions of time, are required, please charge Deposit Account No. 08-0750.

**I. REAL PARTY IN INTEREST**

The real party in interest in the present case is Bausch & Lomb Incorporated.

**II. RELATED APPEALS AND INTERFERENCES**

There are no other related Appeals or Interferences known to Appellant.

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**III. STATUS OF CLAIMS**

Currently pending claims 1, 2, 3, and 4 stand rejected under 35 U.S.C. §103 and are being appealed. Claims 3 and 4 were originally filed with the application, and claims 1 and 2 have previously been amended.

**IV. STATUS OF AMENDMENTS**

No amendment was filed subsequent to the final rejection. This is because essentially the same arguments have previously been presented to the Examiner, and have not been accepted by the Examiner to date.

**V. SUMMARY OF CLAIMED SUBJECT MATTER**

The present invention relates to a fitment 98 that is an elongated connector providing a conduit for aspirant to flow from a pump cartridge 62 to an interior of a collection bag 64. Fitment 98 has opposing ends. A first end is structured for attachment to the pump cartridge 62 and the second end is positioned within the interior of bag 64. A notch 100 ensures that as a vacuum is pulled through the aspiration path, the collection bag 64 cannot completely collapse around the opening in fitment 98. This notch 100 ensures that a sufficient amount of air will be contained within collection bag 64 to vent any inappropriately high vacuum level that has built up in the aspirant path.

**VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL**

The ground of rejection being reviewed is that Claims 1-4 have been improperly rejected under 35 U.S.C. §103 as being unpatentable over Wortrich (US Patent 4,963,131) in view of Sato et al. (US Patent 4,416,772).

**VII. ARGUMENTS****35 USC § 103 REJECTION**

The presently pending claims 1-4 stand rejected under 35 USC § 103a as being unpatentable over US Patent 4,963,131 in view of 4,416,772. The rejection is improper as the combination of the '131 patent and the '772 patent would not result in the present invention as claimed.

The present invention is directed to a novel collection bag for allowing an ophthalmic system to be air vented during surgery to alleviate a build-up of vacuum in the aspiration line. See the present application at paragraph 41. This is in stark contrast to the teaching of the '131 patent that teaches fluid venting and not air venting. The '131 patent teaches venting the aspiration line with fluid from the irrigation supply. See specification generally and col. 6, lines 1-18 specifically. The '131 patent does not encounter the problem identified in the present invention – providing sufficient air in the collection bag in order to vent the aspiration line – because the '131 patent relies solely on fluid venting to solve the excess vacuum condition in the aspiration line. Therefore, someone aware of the '131 patent would not even be concerned with the fitments of the collection bag for venting and would see no reason to combine the '131 patent teaching with the teachings of the '772 patent. Furthermore, it is not clear what the combination of the '131 patent and the '772 patent would render as they are based on completely separate fields of technology (ophthalmic surgery and blood filtering) and concern disparate solutions to different problems.

The '772 patent is not pertinent to the present invention because the '772 patent is directed to blood filtering and not ophthalmic surgery to air-vent an aspiration path as specifically claimed. There is no teaching or suggestion in the '772 patent regarding the

need for ensuring that a sufficient amount of air remains in the collection bag. Rather the '772 patent is simply concerned with maintaining the pressure in the filter bag at atmosphere.

Simply no one skilled in the art would have considered either the '131 patent or the '772 patent in trying to overcome the problem solved by the claimed present invention. In fact, if the two teachings were to be combined the notched elements 22 of the '772 patent would have no utility in the fluid venting scheme taught by the '131 patent.

As the rejection of claims 2-4 depend from independent claim 1, based on the above arguments, they should also be in condition for allowance.

In addition, the combination of Wortrich and Sato et al. would not result in a fitment attached to a pump cartridge function in any manner which is claimed. Sato et al. teaches a rotary pump with a collection bag having an input aspiration line for depositing aspirant from a surgical site and a separate air vent connected to the collection bag (see FIGs. 4 and 11). The air vent of Sato et al. allows atmospheric air to always be pulled into the collection bag and therefore, no pressure differential exists between the interior of the collection bag and atmosphere. Therefore, the structure of a fitment connecting the aspiration line to collection bag is irrelevant for providing a sufficient amount of air in the bag to air vent an aspiration path. The improper combination of Wortrich with Sato et al. is clearly illustrated in the teachings of Sato et al. which is directed to the filtering of body fluids and especially blood and not to air venting an aspiration path.

Claim 1 has been amended to distinguish the present invention from the prior art, and to clearly illustrate the non-analogous nature of Sato et al. Specially, claim 1 has been amended to claim an ophthalmic aspiration collection bag with the fitment connected to an ophthalmic pump cartridge, wherein the notch allows the surgeon to air vent an aspiration path during surgery to prevent collapse of an eye of a patient. One skilled in the art would not have considered Worrich or Sato et al. when trying to ensure the collection bag of an ophthalmic pump cartridge would have sufficient amount of air to allow the aspirant path to be air vented during ophthalmic surgery.

There is no teaching in Sato et al. regarding devices or the need for ensuring that a sufficient amount of air remains in the collection bag, because the filter of Sato et al. ensures that the interior of the bag is at the same pressure as atmosphere. Similarly, there is no teaching in Worrich to provide a device to ensure that a sufficient amount of air remains within the collection bag to vent an aspiration path, rather, the teaching of Worrich teaches the use of irrigation fluid to relieve the vacuum in the aspiration path. Worrich is unconcerned with the amount of air available in the collection bag.

One skilled in the art simply would not have even considered Worrich let alone, be lead to the present invention by Worrich or Sato et al. or the combination of Worrich and Sato et al.

As the C.C.P.A. has stated:

In resolving the question of obviousness under 35 U.S.C. §103, we presume full knowledge by the inventor of all prior art in the field of his endeavor. However, with regard to prior art outside the field of his endeavor, we only presume knowledge from those arts reasonably pertinent to the particular problem with which the inventor was involved.

*In re Wood*, 599 F.2d 1032, 202 USPQ 171, 174 (C.C.P.A. 1979)

The Federal Circuit has further said

A reference is reasonably pertinent if . . . it is one which, because of the matter with which it deals, logically would have commended itself to the inventor's attention in considering his problem. . . . If a referenced disclosure has the same purpose of the claimed invention, the reference relates to the same problem. . . . [I]f it is directed to a different purpose, the inventor would accordingly have less motivation or occasion to consider it.

*In re Clay*, 966 F.2d 656, 23 USPQ 2d 1058, 1060-61 (Fed. Cir. 1992)

In the present case, the field of endeavor of Wortrich is similar to that of the present invention but the solution to relieving the vacuum is completely different. Sato et al. is directed to a blood filtering apparatus and the present invention is related to a fitment for attachment to an ophthalmic aspiration collection bag to provide sufficient air for air venting during surgery to prevent collapse of an eye. Therefore, as the C.C.P.A. and the Federal Circuit have stated, such a reference by Sato et al. would not have been considered by one skilled in the art of ophthalmic aspiration collection bags because the purpose of the present invention and the purpose of Sato et al. are completely different.

By definition, an obviousness rejection is based on the fact that all limitations are not found within a single prior art reference. *Connell v. Sears, Roebuck & Co.*, 722 F.2d 1542 (Fed. Cir. 1983). The Examiner is permitted to combine prior art references or singly modify a prior art reference in order to construct an obviousness rejection.

Applicants challenge the use of the Wortrich and Sato et al. references as irrelevant to the instant application. Additionally, applicants reject the combination of the Wortrich and Sato et al. references based on a lack of motivation to combine the references.



The Sato et al. prior art cited by the Examiner is not within the field of endeavor of the applicant and has improperly been cited against the pending claims. The instant application is directed to a notched fitment for ensuring a sufficient amount of air is maintained in a collection bag to relieve a vacuum in the aspiration path. The Sato et al. reference is directed to a body cavity filtering apparatus. If the prior art is from a non-analogous field it is improper to use such art to reject the subject claims. See, *In re Watter*, 147 F.2d 685, 64 USPQ 571 (C.C.P.A. 1945). See also, *Wang Labs., Inc. v Toshiba Corp.*, 993 F.2d 858, 26 USPQ 2d 1767 (Fed. Cir. 1993).

The following quote from *In re Oetiker* is particularly relevant in the present case.

The Federal Circuit stated:

It has not been shown that a person of ordinary skill, seeking to solve a problem of fastening a hose clamp, would reasonably be expected or motivated to look to fasteners for garments. The combination of elements from non-analogous sources, in a manner that reconstructs the Applicant's invention only with the benefit of hindsight, is insufficient to present a prima facie case of obviousness. There must be some reason, suggestion, or motivation found in the prior art whereby a person of ordinary skill in the field of the invention would make the combination. That knowledge cannot come from the Applicant's invention itself . . . Oetiker's invention is simple. Simplicity is not inimical to patentability.

*In re Oetiker*, 977 F.2d 1443, 24 U.S.P.Q. 2d 1443 (Fed. Cir. 1992)

As in *Oetiker*, the present invention has been reconstructed with the benefit of hindsight. No skilled person would look to the blood filtering arts for a solution to improve air venting an aspiration line in ophthalmic surgery. It is simply improper to use the present invention and cobble disparate prior art together to attempt to reconstruct Applicant's invention.

As the C.C.P.A. has stated:

In resolving the question of obviousness under 35 U.S.C. §103, we presume full knowledge by the inventor of all prior art in the field of his endeavor. However, with regard to prior art outside the field of his endeavor, we only presume knowledge from those arts reasonably pertinent to the particular problem with which the inventor was involved.

*In re Wood*, 599 F.2d 1032, 202 USPQ 171, 174 (C.C.P.A. 1979).

The Federal Circuit has further said

A reference is reasonably pertinent if . . . it is one which, because of the matter with which it deals, logically would have commended itself to the inventor's attention in considering his problem. . . . If a referenced disclosure has the same purpose of the claimed invention, the reference relates to the same problem. . . . [I]f it is directed to a different purpose, the inventor would accordingly have less motivation or occasion to consider it.

*In re Clay*, 966 F.2d 656, 23 USPQ 2d 1058, 1060-61 (Fed. Cir. 1992).

In the present case, the field of endeavor of Sato et al. is different from that of the present invention. Therefore, as the C.C.P.A. and the Federal Circuit have stated, such a reference by Sato et al. would not have been considered by one skilled in the art of vacuum relief in ophthalmic surgery because the purpose of the present invention and the purpose of Sato et al. are completely different.

The recent Supreme Court decision in *KSR International Co. v. Teleflex Inc. et al.*, 550 U.S. \_\_\_\_ (2007), does not effect of the above arguments and citations. KSR dealt with an obvious modification of an adjustable automotive foot pedal based on other automotive foot pedal prior art. No such similar situation exists in the present case. The present invention allows for a simple, inexpensive, elegant solution to allow air

venting in the aspiration path. This advantage has nothing to do with the blood filtering of Sato et al.

The Examiner has given little or no weight to the functional language of the claims that was added to distinguish the present claimed invention from the cited art. Such a position by the Examiner is in complete opposition to long-standing law. Specifically, as stated by the C.C.P.A.:

We take the characterization "functional", as used by the Patent Office and argued by the Parties, to indicate nothing more than the fact that an attempt is being made to define something (in this case, a composition), by what it *does* rather than by what it *is* (as evidenced by specific structure or material, for example). In our view, there is nothing intrinsically wrong with the use of such a technique in drafting patent claims. Indeed, we have even recognized in the past the practical *necessity* for the use of functional language.

*In re Swinehart*, 439 F.2d 210, 169 USPQ 226, 228-29 (C.C.P.A. 1971). See also *In re Bisley*, 197 F.2d 355, 94 USPQ 80, 83 (C.C.P.A. 1952).

Therefore, the functional language of the present claims clearly distinguishes the present invention from the prior art, and should be given patentable weight and the pending claims allowed.

Simply put, no one skilled in the art of ophthalmic surgery would look to the cited prior art for teaching or motivation, let alone come up with the claimed invention.

Therefore, in view of the above arguments, it is respectfully submitted that the present invention is in condition for allowance, and such allowance is requested at an early date.

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**VIII. CLAIMS APPENDIX****1. (Currently Amended)** A fitment for attachment to an ophthalmic aspirant

collection bag comprising:

an elongated connector connected to a ophthalmic pump cartridge providing a conduit for aspirant to flow from the pump cartridge to an interior of the collection bag;

the connector having opposing ends wherein a first end is structured for attachment to the pump cartridge and a second end positioned within the interior of the collection bag is structured to form at least one notch in the second end of the connector; and

wherein the notch acts to prevent the collection bag from sealing off the conduit during surgery so that a sufficient amount of air will remain within the bag to allow a surgeon to air-vent an aspiration path during surgery to prevent collapse of an eye of a patient.

**2. (Previously Presented)** The invention of claim 1, wherein the fitment and the collection bag are heat-sealed together, such that no adhesive is required to form a liquid-tight seal between the bag and the fitment.**3. (Original)** The invention of claim 2, wherein a sealing-ring is formed between the opposing ends for providing a surface to seal the bag to the fitment.**4. (Original)** The invention of claim 1, wherein the second end includes two notches formed in opposing sides of the second end.

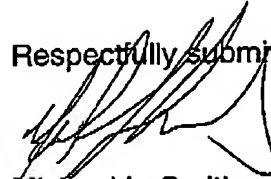
**IX. EVIDENCE APPENDIX**

None

**X. RELATED PROCEEDINGS APPENDIX**

None

Respectfully submitted,



Michael L. Smith  
Reg. No. 35,685

DATE: June 28, 2007

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